### Safety & Environmental Product Stewardship Initiatives

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#### Objective

To provide recommendations to align environmental, health and safety practices with new medical device/diagnostic product launches to yield:

√ Customer benefits and

√ Financial gains/cost savings.

# Imagine products with the following environmental impacts:

- Chemicals prohibited for your sites' or customers' waste discharge, such as mercury (thimerosol) used as a preservative above waste discharge limits, other heavy metals, phenols, formaldehyde.
- Ozone-depleting substances requiring special identification markings on products.
- <u>Special DOT/IATA shipping requirements</u> for reagents or biohazardous materials that are not properly identified.
- Materials that exceed production site's permitted levels. Such as a process discharge of a waste product that violates site's waste water restrictions for heavy metals.
- Packaging with large fees in certain countries due to non-recyclable components.
- Packaging with <u>restricted delivery routes</u> due to hazardous components.



## Imagine products with the following <u>safety</u> impacts:

- Regulated carcinogens requiring employee air sampling/medical surveillance that is not completed, i.e., reagents contain formaldehyde, methylene chloride.
- Reactive materials that must be specially stored, i.e., picric acid dries up and becomes shock-sensitive.
- Chemicals where gloves/engineering controls/training are not identified, i.e., chloroform used as cleaning agent without proper gloves and "hazard communication" training.
- Chemicals where <u>spill response pre-planning is not addressed</u>, i.e., highly toxic solvent requires special air monitoring devices to ensure clean-up.
- No MSDS upon reagent release for sale.
- Production steps that do not address <u>ergonomic concerns</u>, i.e., screw torquing requirements for sub-assembly result in carpal tunnel syndrome.



## Typical EHS "Deliverables" & Product Development/Launch

FEASIBILITY	PRODUCT SPECS	PRODUCT DEVELOPMENT	MANUFACTURE	SALES/SUPPORT
	Permit modifications  Facility modifications/engineerin g controls/ventilation needs  Risk assessment for chemical, biological, radioactive, physical hazards	•SOP creation including EHS components •SOP modification if required •Employee training •Employee medical surveillance if required •Waste management determinations •Emergency response pre-planning •Instrument "serviceability" •Outside supplier raw materials review		•Customer questions re: safety/disposal •Logistics restrictions •Expired product disposal costs
		<ul> <li>MSDS creation</li> <li>Hazardous material packaging/labeling determination</li> <li>Selected market manufacturing/ labeling/repackaging</li> <li>Manufacturing disposal/energy costs</li> </ul>		



### Typical EHS <u>Proactive</u> Actions & Product Development/Launch

FEASIBILITY	PRODUCT SPECS	PRODUCT DEVELOPMENT	MANUFACTURE	SALES/SUPPORT
design for environment principles.  • Develop	Permit modifications  Facility  modifications/engineering  controls/ventilation needs  Risk assessment for  chemical, biological,  radioactive, physical  hazards	SOP creation including EHS components  SOP modification if required  Employee training  Employee medical surveillance if required  Waste management determination  Emergency response pre-planning  Instrument "serviceability"  Outside supplier raw materials review  MSDS creation  Hazardous material packaging/labeling determination  Selected market manufacturing/ labeling/repackaging  Manufacturing  disposal/energy costs		•Customer questions re: safety/disposal •Logistics restrictions •Expired product disposal costs •Monitor world-wide regulatory trends & emerging issues



### Challenges

- Avoiding perception that EHS is a potential bottleneck to product development timelines.
- Building relationships with key internal customers, especially project management, marketing and R&D.
- Complexity of worldwide regulatory market and emerging trends.
- Quantifying financial advantages.



## Cost Benefits of Product Stewardship

- Improved safety and environmental regulatory compliance (programs are proactive vs. reactive).
- Adequate capital/expense planning for internal improvements needed to manufacture goods.
- Reduced packaging costs/duties.
- Improved time to market (all requirements are predicted and addressed).
- Increased marketability of goods (due to environmental or safety benefits to customer).
- Waste reduction for manufacturer and/or customer.

